

elongated tubular member;

generating a laser beam having a wavelength of between 1.4 and 2.2 microns;

directing the beam into the proximal end of the fiber optic cable;

positioning the distal end of the fiber optic cable at the surgical site; and

removing tissue at the surgical site with the laser beam.

58. A method as recited in Claim 57 wherein the laser beam is generated by a Ho:YAG laser.

59. A method as recited in Claim 57 wherein the laser beam is generated by a Ho:YLF laser.

REMARKS

In response to the Examiner's Action of September 16, 1993, Applicant respectfully requests reexamination and reconsideration. Applicant has amended claims 71-83 to change the numbering of these claims to 44-56 respectively, in accordance with the second paragraph of page 2 of the Examiner's Action. In addition, dependent claims 72, 73, 74, 75, 78, 79, 81 and 82 have been amended to change the number of the claim from which they are dependent to conform to the

renumbering of the claims. Finally, Claims 57-59 have been added to this application by amendment.

At page 3 of his action, the Examiner stated that claims 44-56 of the application have been copied from the Boutacoff patents, and are not patentable to the Applicant because Applicant's disclosure does not require that the tissue be irrigated while ablation occurs, nor that the tissue be maintained in a fluid field. Based upon this determination, the Examiner objected to the specification under 35 U.S.C. §112 as failing to provide an enabling disclosure for the invention recited in claims 44-56, and rejected these claims under §112 for the same reasons. As a result, the Examiner refused to initiate an interference because claims 44-56 were found not to be patentable to Applicant. Furthermore, the Examiner refused to initiate an interference because Applicant's claims were found not to be directed to the same invention as the claims in the Boutacoff patents, based upon the fact that Applicant recites a wavelength range of 1.4-2.2 microns while the Boutacoff patents recite a 1.8-2.2 micron wavelength range.

The Examiner's objection to the specification and rejection of claims 44-56 are respectfully traversed. Applicant also respectfully traverses the Examiner's refusal to initiate an interference. The claims as presented are believed to be in allowable condition, and to define the same patentable

invention as the claims of United States Patents Nos. 5,037,421 and 5,147,354 (hereafter collectively the "Boutacoff patents"). Thus, it is believed that this application is in condition for the declaration of the requested interference with the Boutacoff patents.

I. Applicant's Specification Fully Supports Claims 44-56 Which Are Not Identical To The Claims Of The Boutacoff Patents And Do Not Include Limitations Directed To Irrigating While Ablating Or Maintaining A Fluid Field

While claims 44-56 of the application have been substantially copied from the claims of the Boutacoff patents, they have not been identically copied and do not include each of the limitations recited in the claims of those patents. Contrary to the Examiner's apparent understanding, none of claims 44-56 requires that the tissue be irrigated while ablation occurs, or that the tissue be ablated while being maintained in a fluid field. Of the independent claims, claims 44 and 49 each merely recite a step of irrigating the surgical site with a liquid medium, claims 53 and 56 each recite a step of transmitting a fluid medium to the surgical site, and claim 50 includes no step at all directed the use of a fluid.

Support is found in Applicant's specification for each and every limitation of claims 44-56, as is set forth in detail on pages 8 and 9 of the first Preliminary Amendment filed April 19, 1993, and on pages 10 and 11 of the Second Preliminary

Amendment filed July 19, 1993. In particular, at page 15, lines 1-10, Applicant's specification describes the disclosed device as including a lumen that is "provided for transmission of a flushing fluid ... to the probe lens tip area to clear the area of blood during surgery." Thus, Applicant's specification fully supports the steps recited in Applicant's claims 44-49 directed to irrigating the surgical site or tissue with a liquid medium, and the steps in claims 53-56 directed to transmitting a fluid medium to the surgical site. Applicant's specification provides a clear and concise description of the invention recited in claims 44-56 that is sufficient to enable any person skilled in the art to carry out the claimed invention, and therefore fully complies with the requirements of 35 U.S.C. §112. Claims 44-56 are patentable to Applicant, and it is respectfully requested that the rejection of claims 44-56 and the objection to the specification under 35 U.S.C. §112 be withdrawn.

II. Claims 44-56 Define The Same Patentable Invention As
The Claims Of The Boutacoff Patents

A. It Is Not Required That Applicant's Specification
Support Every Limitation Of The Boutacoff Claims

To be entitled to the declaration of an interference, Applicant need not identically copy the claims of the Boutacoff patents, and therefore Applicant's specification need not support each and every limitation of the claims of those

patents. See e.g., Heymes v. Takaya, 6 USPQ2d 2055, 2056 (BPAI 1988) ("Under the present rules an applicant is not required to copy a patent claim exactly, and the applicant need only present claims drawn to the same patentable invention as the "count" of the interference."). As described in the MPEP at §2306:

The requirement that the claims of the application and of the patent define the same patentable invention in order for an interference to exist does not mean that the application claim or claims must necessarily be identical to the corresponding claim or claims of the patent. All that is required under present practice is that a claim of the application be drawn to the same patentable invention as a claim of the patent. An application claim is considered to be drawn to the same patentable invention as a patent claim if it recites subject matter which is the same as (35 U.S.C. 102) or obvious in view of (35 U.S.C. 103), the subject matter recited in the patent claim. 37 C.F.R. 1.601(n). The test is analogous to that applied for double patenting, i.e., if the applicant's claims would have been subject to a double patenting rejection of the "same invention" or "obviousness" type if the patent and application were by the same inventive entity, then the application and patent claim are directed to the same invention. (emphasis added).

As seen from the foregoing, to be entitled to the declaration of an interference, the claims of the patent and the claims of the application must only define the same patentable invention. Applicant's specification need only support Applicant's claims that correspond to the count, and need not support either the Count or the

claims of the interfering Boutacoff patents. See Fujie v. Verhagen, 13 USPQ2d 1986, 1987 (BPAI 1989) (noting that a party to an interference need only support its own claims corresponding to the count, and need not support any limitation that is not recited in its own claims). This fact is demonstrated by Example 19 set forth at MPEP §2309.01, reproduced below:

Example 19: Under 37 C.F.R. 1.606, the PTO will continue to follow the practice announced in *Ex parte Card and Card*, 1904 C.D. 383 (Comm'r.Pat.). Patent J contains claim 1 (method of mixing, grinding, and heating). Application AC contains patentable claim 8 (method of mixing and heating) and does not disclose or claim a grinding step. In the context of the inventions disclosed in patent J and application AC, a method of mixing, grinding, and heating is the same patentable invention as a method of mixing and heating. Under current practice, it would be said that "grinding" is an "immaterial" limitation in claim 1 of patent J. Under 37 C.F.R. 1.606, the fact application AC does not disclose grinding would not preclude an interference. If an interference is declared, there will be one count (method of mixing and heating). Claim 1 of patent J and claim 8 of application AC would be designated to correspond to the count. (emphasis added).

In Example 19, application AC "does not disclose or claim a grinding step" such as the one claimed in claim 1 of patent J. (emphasis added). Nevertheless, since the grinding step was not considered to render the claims of patent J separately patentable over the claims of application AC, an interference would be declared. In

the present application, as in Example 19, an interference is proper even if Applicant's specification does not disclose the steps of irrigating while ablating or maintaining a fluid field as recited in the claims of the Boutacoff patents, because like Example 19, these steps do not render the claims of the Boutacoff patents separately patentable over Claims 44-56 of the present application.

B. It Is Not Required That The Boutacoff Specification Support Applicant's Claims

Claims 44-56, as well as the Proposed Count, recite the generation of a laser beam having a wavelength of between 1.4 and 2.2 microns. At page 3 of the Office Action, the Examiner states that he does not consider these claims to be directed to the same invention as is described in the Boutacoff patents "because Applicant's claims cover a wavelength range unsupported by the patent disclosures". The Examiner has misapplied the standard for determining whether the claims of the application and the Boutacoff patents are directed to the same invention.

As demonstrated by MPEP §2309.01 Example 19, the specification of an application in interference with a patent need not support the claims of the patent. Similarly, for the

requested interference to be initiated, the Boutacoff patents need not support Applicant's claims 44-56. See e.g., MPEP §2309.01, Example 15. Rather, the proper test for determining whether the claims of the Boutacoff patents define the "same patentable invention" as claims 44-56 is set forth at 37 C.F.R. §1.601(n). Under that test, the claims of the present application define the same patentable invention as those of the Boutacoff patents if they recite subject matter which is the same as (35 U.S.C. 102) or obvious in view of (35 U.S.C. 103) the subject matter recited in the patent claims. See also MPEP §2306.

C. The Claimed Ranges of 1.4-2.2 Microns and 1.8-2.2 Microns Are Not Patentably Distinct

The Boutacoff patents disclose and claim a laser beam having wavelengths within Applicant's claimed range of 1.4-2.2 microns. Thus, if the subject matter recited in the Boutacoff claims (i.e., a range of 1.8-2.2 microns) was prior art to the present application, it would anticipate claims 44-56 and render them unpatentable under §102. See e.g., Titanium Metals Corporation of America v. Banner, 227 USPQ 773, 779 (Fed. Cir. 1985) ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is "anticipated" if *one* of

them is in the prior art.") (emphasis in original); In re Gosteli, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989) (noting that under §102, the disclosure of a species by the prior art prevents patenting of a corresponding genus claim).

Furthermore, if the subject matter of claims 44-56 was prior art to the claims of the Boutacoff patents, those claims would also be anticipated. The wavelength ranges claimed by Applicant and the Boutacoff patents each define lasers that are effective for the same purpose, namely for performing surgical procedures, such as tissue removal, using a fiberoptic delivery system. Therefore, since the narrower range of 1.8-2.2 microns has not been demonstrated to be critical relative to the broader range of 1.4-2.2 microns or to achieve any unexpected results relative to that broader range, it is not patentable thereover. See In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). To establish the patentability of a claimed range that is subsumed within a range disclosed by the prior art, an applicant "must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range." Id. at 1936 (emphasis in original).

Evidence of the inability of Boutacoff to establish patentability of his range over the range of Applicant herein

is found in the file histories of the Boutacoff patents. During the prosecution of the parent to the application from which the first Boutacoff patent issued, the European counterpart to Applicant's application was cited as prior art in rejecting the claims as presented. (See Paper #6 of the file history of serial no. 07/418,942. Copies of each of the file histories related to the Boutacoff patents are enclosed herewith as Exhibits A-D). In response to this rejection, Boutacoff did not argue that his claimed range of 1.8-2.2 microns was patentable over Applicant's disclosed range of 1.4-2.2 microns or that Boutacoff's claimed range achieved unexpected results relative to applicant's range. Rather, Boutacoff added additional limitations to his claims, the additional limitations relating to the steps of irrigating while ablating and maintaining a fluid field. (See Paper #7 of the 07/418,942 file history). Thus, Boutacoff implicitly admitted that the Examiner was correct in his determination that Boutacoff's claimed range is not separately patentable over Applicant's claimed range.

For these reasons, Boutacoff's claimed range of 1.8-2.2 microns cannot be considered to be a critical range that is separately patentable over applicant's claimed range. Id. at 1936.

D. The Steps Of Irrigating While Ablating And Maintaining A Fluid Field Do Not Render The Boutacoff Claims Separately Patentable Over Claims 44-56 Because These Steps Were Well Known In The Art

As stated above, Boutacoff attempted to distinguish the claims of his patents over the European counterpart to the present application by including steps directed to irrigating while ablating, and maintaining the tissue in a fluid field during the ablating step. However, these steps were old in the art and are taught specifically in U.S. Patents Nos. 4,448,188 (Loeb) and 4,732,448 (Goldenberg), each of which is prior art to the Boutacoff patents but was not of record or considered during the prosecution of the Boutacoff applications. Copies of the Loeb and Goldenberg patents were submitted in connection with the parent of this application and are again enclosed herewith for the convenience of the Examiner as Exhibits E and F respectively.

The Loeb and Goldenberg patents each teach irrigation of a surgical site during the ablation process, and Loeb specifically teaches such irrigation in connection with a laser operating at infrared wavelengths. (see Loeb, col. 2, lines 13-31; col. 4, lines 4-64; col. 9, lines 60-63; and Goldenberg at col. 3, lines 29-38; and col. 8, lines 30-46). At col. 8, lines 31-40, Goldenberg states that when a lesion is ablated by

a laser, ablated products can sputter onto the tip of the fiberoptic, but that debris is prevented from settling on the fiberoptic by "interposing a continuous layer of saline solution between the tip of the fiber and the lesion." (emphasis added). Similarly, at col. 4, lines 43-46, Loeb states that the type of flushing fluid can be selected to maximize the desired transparency to a particular laser wavelength, thus clearly indicating that the flushing fluid is maintained in the area of the surgical site during the ablation process.

Since the steps of irrigating while ablating and maintaining a fluid field are old in the art, they do not patentably distinguish the Boutacoff claims from claims 44-56 of the present application. Under the test set forth at 37 C.F.R. §1.601(n) and MPEP §2306, it is clear that the claims of the Boutacoff patents define the same patentable invention as claims 44-56, because the subject matter of the Boutacoff claims would have been obvious over the subject matter of claims 44-56, in view of either the Loeb or Goldenberg patents.

III. Since The Steps Of Irrigating While Ablating And Maintaining A Fluid Field Do Not Render the Boutacoff Claims Separately Patentable, Applicant Alternatively Proposes A Broader Count That Does Not Include Any Step Directed To The Use Of Fluid

ALTERNATE PROPOSED COUNT

A method of performing a surgical procedure for the removal of biological tissue comprising the steps of:

generating a laser beam having a wavelength of between 1.4 and 2.2 microns;

directing the beam into one end of a fiber optic cable, with the other end of the fiber optic cable defining the delivery end thereof;

positioning the delivery end of the fiber optic cable at the surgical site; and

removing tissue at the surgical site with the laser beam.

The Alternate Proposed Count is identical to the Proposed Count, except that the last step relating to transmitting a fluid medium to the surgical site has been removed. As stated above in Section II(D), the steps of transmitting fluid to the surgical site and maintaining a fluid field during ablation were well-known in the art, as evidenced by the Loeb and Goldenberg patents. Thus, these steps add no separately patentable feature to claims 44-49 and 53-56, or to the claims of the Boutacoff patents. Claim 50 is virtually word-for-word identical to the Alternate Proposed Count and does not contain any such transmitting or maintaining steps. Claims 51 and 52 are dependent therefrom and define the type of laser.

Since, as set forth in Applicant's first and second Preliminary Amendments herein, claims 44-56 of this application and all of the claims of the Boutacoff patents correspond to and define the same patentable invention as the Proposed Count, each of claims 44-56 also defines the same patentable invention as the Alternate Proposed Count, and all of claims 44-56 in this application correspond to the Alternate Proposed Count. For these same reasons, claims 1-6 of the '421 Boutacoff patent and claims 1-9 of the '354 Boutacoff patent all correspond to the Alternate Proposed Count.

Claims 57-59 have been added to the present application and also correspond to both the Proposed Count and the Alternate Proposed Count. These claims do not include any step directed to transmitting fluid to the surgical site. Claim 57 is identical to claim 53 herein, except for the deletion of the step of "transmitting a fluid medium to the surgical site." Claim 58 and 59 depend from claim 57 and recite additional limitations that correspond to those respectively recited in claims 54 and 55. Claims 57-59 have been substantially copied from claims 7-9 of the '354 Boutacoff patent and claim the same patentable invention. Claims 57-59 also define the same patentable invention as the Alternate Proposed Count, for the same reasons as claims 53-55.

The following is an application of each term of claims 57-59 to Applicant's specification (claims 44-56 were applied in the first and second preliminary amendments):

Elements of Claims 57-59

1. A method of performing a surgical procedure for the removal of biological tissue;
2. Providing a fiber optic cable with a proximal end and a distal end (Claim 80);
3. With the fiberoptic cable being surrounded by an elongated tubular member (Claim 80);
4. Generating a laser beam having a wavelength of between 1.4 and 2.2 microns;
5. Directing the beam into a proximal end of a fiber optic cable;

Elements of Claims 57-59

6. Positioning the distal end of the fiber optic cable at the surgical site;

Support in Application
Serial No. 049,157

Page 6, Lines 11-24;

Page 13, Lines 10-18;
Page 17, Lines 8 through
Page 19, Line 6;
Page 21, Lines 18-22;
Page 13, Lines 15-18;

Page 6, Lines 1-6;

Page 13, Lines 12-15;
Page 21, Lines 19-20;

Support in Application
Serial No. 049,157

Page 1, Lines 13-21;
Page 14, Lines 17-25;
Page 21, Lines 21-23;
Page 31, Lines 1 and 2;
Column 9, Lines 3-16 of
U.S. Patent No. 4,850,351,
the specification of which
is incorporated by refer-
ence in the subject
application at Page 20,
Lines 3-8;

7. Removing tissue at the surgical site with the laser beam; Page 6, Lines 11-14;

8. Wherein the laser beam is generated by a Ho:YAG laser; Page 10, Line 5;

9. Wherein the laser beam is generated by a Ho:YLF laser; Page 10, Line 4.

If the Examiner determines that neither the Proposed Count, nor the Alternate Proposed Count is acceptable, Applicant would be willing to consider a phantom count suggested by the Examiner. Applicant would prefer that the Alternate Proposed Count be selected, because this Count more broadly defines the common patentable invention claimed in the present application and the Boutacoff patents.

The selection of the Alternate Proposed Count would closely track Example 19 recited in MPEP §2309.01, which is reproduced above in Section II(A). As shown in that example, the fact that the Boutacoff patents describe and claim an additional step that does not render those claims separately patentable does not prevent the declaration of an interference with the present application. As described in Example 19, the interference should be declared with one count, and each claim of the present application and of the Boutacoff patents should be designated as corresponding to the count.

It is respectfully submitted that Applicant has complied with all of the requirements of 37 CFR §1.607. Therefore, it is requested that the Examiner declare an interference between this application and the two Boutacoff patents based on the Alternate Proposed Count, and that each of claims 44-59 herein being designated as corresponding to the Count. It is further requested that all of claims 1-6 of the '421 Boutacoff patent and claims 1-9 of the '354 Boutacoff patent be designated as corresponding to the Count.

IV. Conclusion

The claims of the present application have not been rejected over prior art, and the rejection of claims 44-56 under §112 has been shown above to be improper. Thus, the claims of the present application have been shown to be patentable to Applicant.

The wavelength range claimed by Boutacoff does not achieve any unexpected results relative to Applicant's claimed range, and therefore these ranges are not patentably distinct. Additionally, the steps of irrigating while ablating and maintaining a fluid field are shown above to have been known in the art, and therefore do not patentably distinguish the subject matter of the Boutacoff claims from that of Applicant's claims. Therefore, Applicant's claims and those of the

Boutacoff patents define the same patentable invention.

In view of the fact that Applicant's claims 44-59 have been shown to be patentable to the Applicant and to define the same patentable invention as the claims of the Boutacoff patents, "an interference should be declared." MPEP §2307.02. Thus, it is respectfully requested that an interference be declared between this application and both Boutacoff patents, based on either the Proposed Count set forth on page 4 of Applicant's amendment of July 19, 1993, or the Alternate Proposed Count set forth herein.

Respectfully submitted,

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